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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/091,609 | 03/05/2002 | Adnan M. M. Mjalli | 41305/271622 | 8253 |

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---|--|
| Office Action Summary | Application No. 10/091,609 | Applicant(s) M. MJALLI ET AL. | |
| | Examiner Laura L. Stockton, Ph.D. | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 19-24 and 39 is/are rejected.
- 7) ☒ Claim(s) 3-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-39 are pending in the application.

Election/Restrictions

Applicants' election of Group I, and the species of Example 9, in the response filed May 7, 2003 was acknowledged in the previous Office Action.

Correction: The election was made with traverse. The traversal was on the ground(s) that searching each group would not be unduly burdensome. Applicants' argument has been considered but has not been found persuasive because separate search considerations are required for each group. In addition, as noted in the previous Office Action, the examination of the generic concept alone was very burdensome as seen by the vast number of references that anticipated the claims.

The requirement is still deemed proper and is therefore made
FINAL.

The generic concept that has been examined, inclusive of the elected species of Example 9, is as follows:

Compounds of Formula (I) where R_2 is definition a) {e.g., R_2 is a group of the formula $-N(R_9R_{10})$, $-NHC(O)R_9$ or $-NHC(O)OR_9$ }.

The generic concept is embraced by claims 1-24 and 39.

Subject matter not embraced by the above identified generic concept and claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **with** traverse in the response filed May 7, 2003.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants' amendment to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 19-24 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, after the “t)” definition under the definitions of R₅, R₆, R₇ and R₈, an “and” should be added before the definition of “u”).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 19-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xue et al. {U.S. Pat. 5,703,092}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim benzimidazole compounds. Xue et al. teach benzimidazole compounds which are structurally similar to the instant claimed compounds. See in Xue et al., for example, wherein A is – $\text{CH}(\text{R}^{11})\text{C}(\text{R}^9)(\text{R}^{9a})\text{CO}_2\text{H}$; R^{11} , R^9 , R^{9a} and R^{14} are each hydrogen; R^2 and R^3 are each a C_{1-6} alkyl substituted with R^{17b} ; R^{17b} is aryl; Q is a benzimidazole substituted with R^5 ; R^5 is C_{1-6} alkyl substituted with R^{20} ; R^{20} is a heterocycle such as piperidinyl (columns 5-8 and 38-40; and especially Example 410 in Table 3 in column 37).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-inflammatory).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful as, for example, an anti-inflammatory. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicants' arguments filed January 2, 2004 have been fully considered. In regard to the rejection of the claims under 35 USC § 103, Applicants argue that Xue et al. fail to teach or suggest modifying a benzimidazole ring to include at least one group of the formula $-Y-C_{1-6}$ alkylene- $NR_{13}R_{14}$. In response, Xue et al. teach that the benzimidazole ring (represented by the Q variable) is substituted with R^5 and R^5 can represent C_{1-6} alkyl substituted with R^{20} ; and R^{20} can represent a heterocycle such as piperidinyl. Note in the instant claims wherein Y is CH_2 and R_{13} and R_{14} can be taken together to form a ring.

Claim Objections

Claims 3-18 are objected to because of the following informalities:
"comprises" should be "is" in each of these claims.

Allowable Subject Matter

The elected species of Example 9 is allowable over the art of record.

Claims 3-18 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of

this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

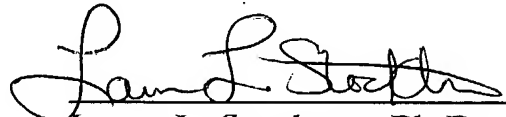
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

April 5, 2004